

ORIGINAL ARTICLE

The diagnosis of chlamydia, gonorrhoea, and trichomonas infections by self obtained low vaginal swabs, in remote northern Australian clinical practice

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Objective: To examine the diagnostic performance of self obtained low vaginal swabs (SOLVS) and polymerase chain reaction (PCR) techniques in the diagnosis of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), and *Trichomonas vaginalis* (TV) infection in a variety of clinical practice settings in remote north western Australia.

Design: A cross sectional field study of microbiological collection techniques in women undergoing gynaecological investigation in remote settings performed by a variety of practitioner types over 10 months.

Participants and setting: 349 women from remote towns and communities in the Kimberley region of north west Western Australia having gynaecological examinations for clinical reasons, well women screening, antenatal screening, and sexual health examinations.

Results: The overall prevalence of infection in the study population based on any positive conventional sample was 9.2%, 7.6%, and 16.1% for CT, NG, and TV respectively. The detection rates for CT and NG by SOLVS were 89% and 96% respectively, compared with 79% and 91% for endocervical swabs and 79% and 83% for first void urine. SOLVS had a sensitivity of 93% for TV detection, equal to that of clinician obtained low vaginal swabs. None of these differences reached statistical significance. A combination of SOLVS and first void urine detected 96% of the CT cases, 100% of the NG cases, and 96% of TV cases.

Conclusions: Self obtained low vaginal swabs are an acceptable, simple and sensitive diagnostic sample for the detection of CT, NG, and TV, and have particular applications in remote clinical practice and as a screening technique.

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The polymerase chain reaction (PCR) and other nucleic acid detection tests have proved to be stable, reliable, and highly sensitive diagnostic techniques in sexual health practice. They have shown themselves to be superior to conventional tests in many settings.¹ Novel applications have been developed to allow patients to participate in the collection of diagnostic samples in order to improve the accessibility and acceptability of testing. First void urine (FVU) has been shown to be suitable for detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG).^{2,3} Patient inserted tampon,⁴ home urine collection,⁵ vaginal douching, and self obtained vaginal, introital or perineal swabs,⁶ have performed well in the detection of CT, NG, and *Trichomonas vaginalis* (TV) in hospital and sexual health clinic settings.^{7–10}

Remote northern Australia has sexually transmitted infection (STI) notification rates several times that of the nation as a whole. This has been attributed to lack of both access to and utilisation of sexual health diagnostic and treatment services.¹¹ Education and screening programmes using improved diagnostic techniques have been shown to impact on community prevalence in remote Australian communities¹² and self tests using tampons have been advocated as a useful diagnostic tool in this setting.⁴

We report the performance and utility of self obtained low vaginal swabs (SOLVS) in the diagnosis of CT, NG, and TV infection in a variety of clinical practice settings in remote north western Australia.

METHOD

Setting

The Kimberley region of Western Australia covers an area of 422 000 square kilometres. Its population of 30 000 perma-

nent residents is located in six small towns and over 75 small, remote, largely Aboriginal communities, mine sites, stations, and outcamps. Sexual health services are provided by clinic based medical officers, remote area nurses, community nurses, and Aboriginal health workers. In year 2000 there were 219 and 218 female NG and CT notifications respectively while the epidemiology of TV is unknown. As TV is not a notifiable disease in Western Australia, there are no routine data collected on this infection.

Study design

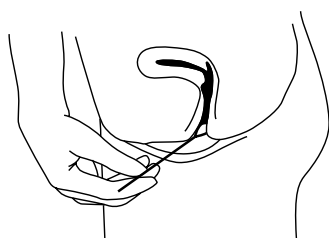
Between July 2000 and April 2001 women having a vaginal examination for any reason were invited to enter the study. Consenting women were asked to provide FVU and a SOLVS test in that order, followed immediately by a clinical examination at which clinicians were asked to collect an endocervical swab (ECS), a low vaginal swab (LVS) for PCR testing, and LVS smear air dried on a glass slide for Gram staining. SOLVS and LVS were collected with plain sterile 15 cm Dacron tipped plastic stemmed swabs and returned to a plain, rigid plastic transport casing. ECS was collected on a slimmer Dacron tipped 15 cm wire stemmed swab. FVU was collected directly into a 50 ml sterile container. Participants were instructed on the SOLVS collection technique by brief explanation using a diagram (fig 1). SOLVS was collected by insertion into the low

Abbreviations: CT, *Chlamydia trachomatis*; ECS, endocervical swab; FVU, first void urine; NG, *Neisseria gonorrhoeae*; PCR, polymerase chain reaction; SOLVS, self obtained low vaginal swabs; TV, *Trichomonas vaginalis*

**This is how to take
your own swab for a
SOLVS PCR test**



Put the tip of the cotton swab stick about 2 cm (length of one finger joint) inside your vagina. Turn the swab around once.



Count to ten whilst leaving the cotton swab stick in the vagina.

Figure 1 SOLVS patient instructions.

vagina past the labia to distance of about 3 cm, held in that position to a count of 10 and rotated once before return to the transport case by the patient.

Information on age, race, clinical indication, symptoms, and clinician type was requested. All specimens were transported at ambient temperature to one of three reception laboratories in the region using routine transport facilities. Thereafter, specimens travelled 2000 kilometres by air transport to the Perth central laboratory for processing the following day.

In line with clinical practice in the study region, a positive result from any conventional collection site was taken to indicate that the patient was infected.

Laboratory technique

All study specimens were handled in the routine manner at the Western Australian Centre for Pathology and Medical Research, Nedlands, Western Australia. Samples were extracted using Chelex 100 resin (BioRad Laboratories, Hercules,

CA, USA).¹³ This method had been shown to efficiently remove PCR inhibitors. An in-house nested multiplex PCR was performed for detection of NG and CT using primers directed at the cryptic plasmid of NG¹⁴ and at the plasmid of CT.¹⁵ All samples positive for NG were retested using two other nested PCRs directed at two separate target sequences within a *N gonorrhoeae* specific probe.¹⁶ Positive results for CT were confirmed by a second PCR directed at a different sequence in the plasmid.¹⁵ Samples were reported positive for NG or CT only if they were positive with all of the PCRs. A nested PCR directed at repetitive DNA sequences was used for TV detection.¹⁷

Statistical analysis

Analysis was conducted using Statistical Package for the Social Sciences (SPSS) version 10.

Ethical approval

Ethical approval was provided by the Western Australian Aboriginal Health Information and Ethics Committee (Health Department of Western Australia, 189 Royal Street, East Perth WA 6004, Australia) with specific approval to collect information on race and Australian Aboriginal ancestry which conforms to National Health and Medical Research Council guidelines.

RESULTS

Results of 349 consented examinations were included; however, not all examinations yielded a full set of the five specified samples. The average age of participants was 28.8 years. Australian Aboriginal women comprised 74% of the study population and 98% of remote participants, while 30% of participants were from remote locations defined as greater than 50 kilometres from a town hospital.

Medical officers provided 63% of the town patient's specimens while nursing staff attended 61% of patients in the remote areas. This reflects the pattern of practice in this region whereby nurse practitioners provide much of the routine clinical care in remote locations.

STI prevalence and diagnostic performance

The overall prevalence of infection in the study population in which a full set of standard tests was collected based on any positive conventional clinical specimen was 9.2%, 7.6%, and 16.1% for CT, NG and TV respectively (table 1).

There were 303 patients in whom SOLVS, ECS, and FVU were collected simultaneously allowing for direct comparison of results in the detection of CT and NG using the finding of infection in either of clinician obtained ECS or FVU as a case definition. There were 286 patients in whom SOLVS, ECS, FVU, and LVS were collected simultaneously allowing evaluation of TV detection by specimen whereby a case is defined as any positive specimen of ECS, FVU, or LVS. Sensitivity, specificity, and predictive values for all specimens are provided in

Table 1 Prevalence of STI infections by clinical indication for examination

| Indication | <i>Chlamydia trachomatis</i> | | | <i>Neisseria gonorrhoeae</i> | | | <i>Trichomonas vaginalis</i> | | |
|------------------|------------------------------|-------------|------|------------------------------|-------------|------|------------------------------|-------------|------|
| | No of patients | No infected | % | No of patients | No infected | % | No of patients | No infected | % |
| Suspected STI | 64 | 14 | 21.9 | 64 | 17 | 26.6 | 57 | 13 | 22.8 |
| Antenatal screen | 70 | 2 | 2.9 | 70 | 1 | 1.4 | 67 | 7 | 10.4 |
| Cervical smear | 119 | 5 | 4.2 | 119 | 1 | 0.8 | 116 | 17 | 14.7 |
| Contraception | 3 | 0 | 0.0 | 3 | 0 | 0.0 | 2 | 0 | 0.0 |
| Other screening | 7 | 0 | 0.0 | 7 | 0 | 0.0 | 7 | 2 | 28.6 |
| Not stated | 40 | 7 | 17.5 | 40 | 4 | 10.0 | 37 | 7 | 18.9 |
| Total | 303 | 28 | 9.2 | 303 | 23 | 7.6 | 286 | 46 | 16.1 |

Table 2 Collection technique diagnostic performance by organism

| | CT | | | NG | | | TV | | | |
|--------------------|-------|------|------|-------|------|------|-------|------|------|------|
| | SOLVS | FVU | ECS | SOLVS | FVU | ECS | SOLVS | FVU | ECS | LVS |
| Sensitivity | 0.89 | 0.79 | 0.79 | 0.96 | 0.83 | 0.91 | 0.93 | 0.89 | 0.87 | 0.93 |
| Specificity | 1.00 | 1.00 | 1.00 | 0.99 | 1.00 | 1.00 | 0.99 | 1.00 | 1.00 | 1.00 |
| Predictive value + | 1.00 | 1.00 | 1.00 | 0.92 | 1.00 | 1.00 | 0.93 | 1.00 | 1.00 | 1.00 |
| Predictive value – | 0.99 | 0.98 | 0.98 | 1.00 | 0.99 | 0.99 | 0.99 | 0.98 | 0.98 | 0.99 |

table 2. A combination of SOLVS and FVU detected 96% of the CT cases, 100% of the NG cases, and 96% of TV cases.

Statistical significance

Using McNemar's test the performance of SOLVS was not statistically different ($p > 0.05$) from that of FVU and ECS against the gold standard of a positive test in any conventional collection method.

DISCUSSION

This study demonstrates that SOLVS PCR is at least as good as conventional clinician obtained samples for identifying CT, NG, and TV infection in a remote population. Furthermore, the high negative predictive values allow the technique to be used as a screening tool for the absence of disease, even in high prevalence populations.

Our study compares samples from a variety of sites and collection methods; however, all tests were submitted to the same laboratory technique making direct comparison possible. The sensitivities observed in our field study are comparable to those found in other hospital and clinic based studies.^{8–10} We were surprised that SOLVS performed as well as ECS collected by clinicians for detection of CT and NG. This may reflect difficulties in properly visualising the cervix, particularly when the examination was carried out in suboptimal circumstances or by less experienced practitioners. For LVS, which are technically easy and unlikely to be improperly collected by clinicians, the yield of TV was the same as for SOLVS, suggesting that the patients did collect samples reliably and correctly.

The effect of first sampling, with a diminishing load of pathogen in subsequent samples, may account for some differences yet LVS, often the last specimen to be taken in the series, performed well against SOLVS in the diagnosis of sub-clinical TV infection. Also, SOLVS samples should not have affected detection by ECS. It is also possible that SOLVS may have had more contact time with pathogens than would clinician obtained samples, resulting in collection of a larger amount of material. Women were instructed to keep the swab in place for about 10 seconds, while busy clinicians may spend less time sampling vaginal secretions or the endocervix.

While the true collection site of a SOLVS could vary substantially from high vagina to perineum or vulva, it clearly performs very well as a diagnostic specimen and is capable of reliable detection of up to three pathogens. The simplicity, low cost of administration, and wide availability of SOLVS is comparable to that of both FVU and tampon self collection techniques. The laboratory handling of vaginal swabs is considerably easier than tampons, which require elution of the tampon with fluid.⁴ Our study demonstrated that SOLVS are successfully collected in a population where many Aboriginal women do not speak standard English, requiring only minimal explanation using a simple instruction sheet (fig 1).

All TV infections identified occurred in the 204 Aboriginal patients, a prevalence of 22.5%, which is consistent with that found in studies in northern Australia and elsewhere.¹⁸ The clinical importance of this finding is yet to be elucidated. Only 20% of TV infections identified by PCR in our study were associated with pelvic symptoms (data not shown). SOLVS may be

a useful method of detecting TV, particularly in epidemiological studies and screening programmes.

SOLVS offers a novel, acceptable technique with a range of applications in clinical settings. It is readily suited to late pregnancy screening for CT and NG as advised in our region. Unskilled clinicians or clinicians unable to examine women for cultural reasons, may use SOLVS in remote settings. In the case of large community based screening, self obtained swabs are easy to handle in the field and the laboratory. Opportunistic screening of young women for CT has been advocated as a cost effective strategy to reduce pelvic pathology¹⁹ and screening high risk populations for TV to reduce HIV transmission has recently been considered.²⁰ SOLVS would be readily suited to both these applications. The collection of both FVU and SOLVS may prove a particularly sensitive technique.

Caution should be exercised in advocating self tests in the investigation of STI, as they are not current clinical best practice. However, these techniques improve equity and reduce access barriers for women at risk of STI, and allow for sensitive and cost effective screening, particularly in remote areas. Further, self testing may empower women to take control of their sexual health, increase sexual health knowledge, and influence behaviour.

CONTRIBUTORS

SCG conceived, designed, managed, and analysed results of the study and was principal author of the paper; DWS assisted in design and analysis of the study and supervised the laboratory specimen analysis; GBH provided the technical expertise in the development and application of the PCR techniques to these specimens.

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